DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

PMG Display Date 8-27-03
Publication Date 8-28-03
Certifier R. LEDESMA

Oral Dosage Form New Animal Drugs; Etodolac

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of American Cyanamid Co. The supplemental NADA provides for a 500-milligram (mg) tablet size of etodolac for oral use in dogs.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *mberson@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, filed a supplement to NADA 141–108 that provides for a 500-mg tablet size of ETOGESIC (etodolac) Tablets used for the management of pain and inflammation associated with osteoarthritis in dogs. The supplemental application is approved as of May 8, 2003, and the regulations are amended in 21 CFR 520.870 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

cv0323 NADA 141-108 NFR

[illegible]

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.870 [Amended]

■ 2. Section 520.870 *Etodolac* is amended in paragraph (a) by removing "150 or 300" and by adding in its place "150, 300, or 500".

Dated: August 13, 2003
August 13, 2003.

cv0323

Steven D. Vaughn D.V.M.

~~Stephen F. Sundlof,~~ Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

B Bodo 8-21-03

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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